

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

In the Matter of:

Medtronic Puerto Rico, Inc.  
Villalba, Puerto Rico

Respondent

In a proceeding under Section 113(a)  
of the Clean Air Act, 42 U.S.C. § 7413(a)(3)

NOTICE OF VIOLATION  
CAA-02-2021-1304

**SUMMARY**

The United States Environmental Protection Agency (“EPA”) Region 2 Director of the Caribbean Environmental Protection Division (“Director”) issues this Notice of Violation (“NOV”), consistent with Section 113(a)(1) of the Clean Air Act (“CAA” or “the Act”), 42 U.S.C. 42 U.S.C. § 7413(a)(1), to Medtronic Puerto Rico, Inc. (“Medtronic” or “Respondent”), the owner and operator of a commercial ethylene oxide sterilization facility located at PR-149 Km. 56.3, in the municipality of Villalba, Puerto Rico. EPA alleges that Respondent violated certain requirements of the Puerto Rico Regulations for the Control of Atmospheric Pollution. This NOV also identifies, as a courtesy, violations of 40 C.F.R. Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities.

**STATUTORY, REGULATORY AND PERMITTING BACKGROUND**

1. Section 302(e) of the Act, 42 U.S.C. § 7602(e), provides that, the term “person” includes an individual, corporation, partnership, association, State, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

2. Section 113(a)(1) of the Act, 42 U.S.C. § 7413(a)(1), provides, in relevant part, that whenever the EPA Administrator finds, on the basis of any information available to the Administrator, that any person has violated or is in violation of any requirement or prohibition of a SIP, the Administrator shall notify the person and the state in which the SIP applies of such finding. Section 113(a)(1) further provides that 30 days after providing such notice, the EPA Administrator may take various actions to address the violation(s).
3. Section 113(a)(3) of the CAA, 42 U.S.C. § 7413(a)(3), authorizes the Administrator to, among other actions, issue an administrative penalty order or bring a civil action against any person whenever, on the basis of any information available to EPA, the Administrator finds that such person has violated or is in violation of any requirement or prohibition of Title I of the Act, or of any regulation promulgated pursuant to Section 112 of the Act, 42 U.S.C. § 7412.
4. Section 114 of the Act, 42 U.S.C. § 7414, authorizes the EPA Administrator to require testing, monitoring, record-keeping, and reporting of information, to enable him or her to carry out any provision of the Act (except certain provisions in Title II) and to assess compliance with, among other requirements, any regulations promulgated under Section 112 of the Act, 42 U.S.C. § 7412.
5. The CEPD Director is authorized by the EPA Administrator through the EPA Region 2 Regional Administrator to make findings of violations, issue notices thereof, and gather information, pursuant to Sections 113 and 114 of the Act. 42 U.S.C. §§ 7413 and 7414. *See* EPA Delegation of Authority 7-6-A; EPA Region 2 Delegation of Authority 7-6-A; EPA Delegation of Authority 7-8; EPA Region 2 Delegation of Authority 7-8.

CAA Section 112

6. Section 112(a) of the Act, 42 U.S.C. § 7412(a), contains the following relevant definitions:
  - a. “Major source” means any stationary source or group of stationary sources located within

a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.

CAA Section 112(a)(1), 42 U.S.C. § 7412(a)(1).

- b. “Area source” means any stationary source of hazardous air pollutants that is not a major source. CAA Section 112(a)(2), 42 U.S.C. § 7412(a)(2).
- c. “Stationary source” means any building, structure, facility, or installation which emits or may emit any air pollutant. CAA Section 112(a)(3), 42 U.S.C. § 7412(a)(3).
- d. “New source” means a stationary source the construction or reconstruction of which is commenced after the Administrator first proposes regulations under this section establishing an emission standard applicable to such source. CAA Section 112(a)(4), 42 U.S.C. § 7412(a)(4).
- e. “Hazardous air pollutant” means any air pollutant listed pursuant to Section 112(b) of the Act, CAA Section 112(a)(6), 42 U.S.C. § 7412(a)(6).
- f. “Owner or operator” means any person who owns, leases, operates, controls, or supervises a stationary source. CAA Section 112(a)(9), 42 U.S.C. § 7412(a)(9).
- g. “Existing source” means any stationary source other than a new source. CAA Section 112(a)(10), 42 U.S.C. § 7412(a)(10).

- 7. Section 112 of the Act requires the EPA Administrator to: (i) publish a list of hazardous air pollutants (“HAPs”), (ii) publish a list of categories and subcategories of major and area sources of those HAPs, and (iii) promulgate regulations establishing emission standards for each such category and subcategory. 42 U.S.C. § 7412(c)(1), (2), and (3).

8. Emissions standards promulgated pursuant to Section 112 are commonly known as National Emissions Standards for Hazardous Air Pollutants (“NESHAPs”). NESHAPs promulgated under the CAA as they existed prior to the 1990 CAA amendments are set forth in 40 C.F.R. Part 61. NESHAPs promulgated under the CAA as amended in 1990 are set forth in 40 C.F.R. Part 63. 40 C.F.R. Part 63 NESHAPs are sometimes known as maximum achievable control technology (“MACT”) standards, because Section 112(d) of the CAA, as amended in 1990, directs EPA to promulgate emissions standards based on the MACT. 42 U.S.C. § 7412(d)(2).

*NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations*

9. Pursuant to Section 112 of the Act, 42 U.S.C. § 7412, EPA promulgated the “Ethylene Oxide Emission Standards for Sterilization Facilities,” which are codified at 40 C.F.R. Part 63, Subpart O, §§ 63.360 *et seq.* (“Subpart O”). *See* 59 Fed. Reg. 62589 (Dec. 6, 1994) (as amended).
10. Pursuant to 40 C.F.R. § 63.360(a), all sterilization sources using 1 ton of ethylene oxide (“EtO”) in sterilization or fumigation operations are subject to the emission standards in 40 C.F.R. § 63.362, except as specified in paragraphs (b) through (e) of 40 C.F.R. § 63.360.
11. 40 C.F.R. §§ 63.360(a) and (g)(4) requires the owner or operator of any sterilization facility with an initial startup date before December 6, 2000, using 1 or more tons of EtO, to comply with the emission standards in 40 C.F.R. § 63.362 for aeration room vents by December 6, 2000.
12. 40 C. F. R. § 63.362(c) provides that the owner or operator of a sterilization source using 1 ton of EtO shall reduce EtO emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.
13. Pursuant to 40 C.F.R. § 63.363(a)(1), the owner or operator of a source subject to emissions standards in 40 C.F.R. § 63.362 shall conduct an initial performance test using the procedures listed in 40 C.F.R. § 63.7 according to the applicability in Table 1 of § 40 C.F.R. § 63.360, the

procedures listed in 40 C.F.R. § 63.363, and the test methods listed in 40 C.F.R. § 63.365.

14. 40 C.F.R. § 63.363(a)(2) requires the owner or operator of all sources subject to the emission standards in 40 C.F.R. § 63.362 to complete performance testing within 180 days after the compliance date for the specific source as determined in 40 C.F.R. § 63.360(g).
15. 40 C.F.R. § 63.363(b) establishes the procedures that the owner or operator of a sterilization source shall use to determine initial compliance with the emission limits under 40 C.F.R. § 63.362(c), the sterilization chamber vent standard and to establish operating limits for the control devices.
16. 40 C.F.R. § 63.363(b)(3) provides that for facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.
17. 40 C.F.R. § 63.363(e) requires the owner or operator of facilities complying with the emissions limits under 40 C.F.R. § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers to provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. The owner or operator shall determine the site-specific operating limits for the operating parameters approved by the Administrator during the required performance test, using the methods approved in 40 C.F.R. § 63.365(g).
18. 40 C.F.R. § 63.363(f) provides that a facility must demonstrate continuous compliance with each operating limit and work practice standard required, except during periods of startup, shutdown, and malfunction, according to the methods specified in 40 C.F.R. § 63.364.

19. 40 C.F.R. § 63.364(a)(1) provides that an owner or operator of a source subject to the emissions standards in 40 C.F.R. § 63.362 shall comply with the monitoring requirements in 40 C.F.R. § 63.8, according to the applicability in Table 1 of 40 C.F.R. § 63.360, and 40 C.F.R. § 63.364.
20. 40 C.F.R. § 63.364(a)(2) requires the owner or operator of an ethylene oxide sterilization facility subject to the emissions standards of Subpart O to monitor the parameters specified in 40 C.F.R. § 63.364. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained.
21. 40 C.F.R. § 63.364(c) provides that for sterilization facilities complying with 40 C.F.R. § 63.363(b) or 63.363(c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with 40 C.F.R. § 63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in 40 C.F.R. § 63.364(c)(4). Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

NESHAP General Provisions—Performance Testing Requirements

22. Pursuant to 40 C.F.R. § 63.360, the owner or operator of sources using 1 ton subject to the provisions of Subpart O must comply with the requirements of 40 C.F.R. Part 63, Subpart A. 40 C.F.R. § 63.360 Table 1 contains the NESHAP Subpart A General Provisions that are applicable to such sources.
23. 40 C.F.R. § 63.7(e)(1) provides that performance tests shall be conducted under such conditions

as the Administrator specifies to the owner or operator based on representative performance (i.e., performance based on normal operating conditions) of the affected source.

24. 40 C.F.R. § 63.7(e)(2) provides that performance tests shall be conducted and data shall be reduced in accordance with the test methods and procedures set forth in 40 C.F.R. § 63.7, in each relevant standard, and, if required, in applicable appendices of Parts 51, 60, 61, and 63 unless the Administrator (i) specifies or approves, in specific cases, the use of a test method with minor changes in methodology. Such changes may be approved in conjunction with approval of the site-specific test plan; or (ii) approves the use of an intermediate or major change or alternative to a test method, the results of which the Administrator has determined to be adequate for indicating whether a specific affected source is in compliance; or (iii) approves shorter sampling times or smaller sample volumes when necessitated by process variables or other factors; or (iv) waives the requirement for performance tests because the owner or operator of an affected source has demonstrated by other means to the Administrator's satisfaction that the affected source is in compliance with the relevant standard.

*NESHAP General Provisions—Notification Requirements*

25. 40 C.F.R. § 63.9(h)(1) provides that the requirements set forth in 40 C.F.R. § 63.9(h)(2) through (h)(4) (notification of compliance status) apply when an affected source becomes subject to a relevant standard.
26. Pursuant to 40 C.F.R. § 63.9(h)(2)(i), when an affected source becomes subject a relevant standard, the owner or operator of such source shall submit to the Administrator a notification of compliance status, signed by the responsible official who shall certify its accuracy, attesting to whether the source has complied with the relevant standard. The notification shall list: (A) the methods that were used to determine compliance; (B) the results of any performance tests,

opacity or visible emission observations, continuous monitoring system (“CMS”) performance evaluations, and/or other monitoring procedures or methods that were conducted; (C) the methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods; (D) the type and quantity of hazardous air pollutants emitted by the source (or surrogate pollutants if specified in the relevant standard), reported in units and averaging times and in accordance with the test methods specified in the relevant standard; (E) if the relevant standard applies to both major and area sources, an analysis demonstrating whether the affected source is a major source (using the emissions data generated for this notification); (F) a description of the air pollution control equipment (or method) for each emission point, including each control device (or method) for each hazardous air pollutant and the control efficiency (percent) for each control device (or method); and (G) a statement by the owner or operator of the affected existing, new, or reconstructed source as to whether the source has complied with the relevant standard or other requirements.

27. 40 C.F.R. § 63.9(h)(2)(ii) provides that the notification of compliance status must be sent before the close of business on the 60<sup>th</sup> day following the completion of the relevant compliance demonstration activity specified in the relevant standard (unless a different reporting period is specified in the standard, in which case the letter must be sent before the close of business on the day the report of the relevant testing or monitoring results is required to be delivered or postmarked). For example, the notification shall be sent before close of business on the 60<sup>th</sup> (or other required) day following completion of the initial performance test and again before the close of business on the 60<sup>th</sup> (or other required) day following the completion of any subsequent required performance test. If no performance test is required but opacity or visible emission observations are required to demonstrate compliance with an opacity or visible emission standard



under this part, the notification of compliance status shall be sent before close of business on the 30<sup>th</sup> day following the completion of opacity or visible emission observations. Notifications may be combined as long as the due date requirement for each notification is met.

*NESHAP General Provisions—Recordkeeping and Reporting Requirements*

28. 40 C.F.R. § 63.10(e)(3)(i) provides that the owner or operator of an affected source required to install a CMS by a relevant standard shall submit an excess emissions and continuous monitoring system performance report and/or a summary report to the Administrator semiannually.
29. 40 C.F.R. § 63.10(e)(3)(vi) provides that one summary report shall be submitted for the hazardous air pollutants monitored at each affected source (unless the relevant standard specifies that more than one summary report is required, e.g., one summary report for each hazardous air pollutant monitored).

*Commonwealth of Puerto Rico Regulations for the Control of Atmospheric Pollution*

30. Pursuant to the Puerto Rico Environmental Public Policy Act, Law No. 9 of June 18, 1970,<sup>1</sup> the Puerto Rico Environmental Quality Board (“EQB”) developed the Puerto Rico Regulations for the Control of Atmospheric Pollution (“RCAP”).
31. By virtue of Law 122 of December 18, 2017, EQB’s functions, services, programs and/or powers were transferred to the Puerto Rico Department of Natural and Environmental Resources (“DNER”).<sup>2</sup>
32. On January 22, 1997, EPA approved DNER’s RCAP, submitted to EPA on September 29, 1995, as part of the federally approved State Implementation Plan (“SIP”) for the Commonwealth of Puerto Rico. 62 Fed. Reg. 3211

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<sup>1</sup> Repealed and superseded by Law No. 416 of September 22, 2004, as amended.

<sup>2</sup> All actions taken by the EQB prior to December 18, 2017 will be referenced as actions taken by the DNER.

33. RCAP Rule 204(H)(1) establishes that at least 60 days before the expiration of a permit to operate, the owner or operator shall file an application for renewal of the permit to operate such source.

### **FINDINGS OF FACT**

The following findings of fact are based on a review of Facility records and an inspection performed by EPA:

34. EPA Region 2 conducted an investigation of Respondent pursuant to Section 114 of the Act, 42 U.S.C. § 7414 (“EPA Investigation”). The EPA Investigation included, in part: a) an on-site inspection of Respondent’s Sterilization Facility; b) multiple information requests made to Medtronic about the Sterilization Facility and its operations; and c) a review of Respondent’s records and data, as provided to EPA subsequent to the on-site inspection and information requests.
35. Respondent owns and operates an ethylene oxide sterilization facility (the “Facility”) located at PR-149 Km. 56.3 in Villalba, Puerto Rico.
36. The Facility has been in operation since 1998.
37. On June 13, 2000, Respondent submitted to EPA and DNER an initial notification letter stating that the Facility became subject to Subpart O on February 16, 2000.
38. The Facility operates under an emission source operating permit, PFE-03-76-0811-0045-I-II-O (“the Permit”), issued by DNER on March 21, 2012, pursuant to RCAP Rule 204.
39. The Permit expired on March 21, 2017.
40. On February 8, 2017, Respondent submitted a permit renewal application to DNER, No.PFE-RG-76-0217-0107-I-II-O. Respondent did not submit the permit renewal application by January 20, 2017, or at least 60 days prior to the Permit’s March 21, 2017 expiration date.

41. On December 6, 2019, EPA Region 2, accompanied by inspectors from the EPA National Enforcement Investigation Center (“NEIC”) (collectively “EPA inspectors”) conducted an on-site inspection of the Facility (“December 2019 Inspection”).
42. The report of the December 2019 Inspection was transmitted to the Respondent on June 26, 2020, by electronic mail.
43. During the December 2019 Inspection, Respondent’s representatives escorted the EPA inspectors through the Facility.
44. During the December 2019 Inspection, the Sterilization Facility was operating 23 sterilization chambers located in three (3) different rooms, each designated as either high-voltage or low-voltage chambers.
45. Each of the 23 sterilization chambers is equipped with its own aeration chamber located directly beneath the sterilization chamber. Each room has a gas chromatograph (GC) to measure EtO using a series of sampling ports.
46. Each of the 23 sterilization chambers is also equipped with a catalytic oxidizer (“Abator” or “catalytic oxidizer”) to control EtO emissions.
47. During the December 2019 Inspection, the EPA inspectors requested the Respondent to provide copy of the Subpart O semi-annual compliance reports required under 40 C.F.R. §§ 63.10(e)(3)(i) and 63.360(a).
48. During the December 2019 Inspection, a Medtronic representative indicated that Respondent had not been submitting semi-annual compliance reports to EPA nor DNER.
49. The last semi-annual compliance report located in EPA’s records is dated February 8, 2016, covering the reporting period of July 1 through December 31, 2015.

50. During the December 2019 Inspection, the EPA inspectors requested Medtronic to provide copy of the initial performance test conducted at the Facility.
51. During the closing meeting of the December 2019 Inspection, Respondent agreed to provide to EPA via electronic mail, the performance test report, EtO consumption logs, the Abators Operation and Installation Manual, the Abators inspection report, records of the Abators preventive maintenance inspections and notice of compliance status, among other information requested by the EPA inspectors.
52. On December 13, 2019, Respondent submitted to EPA, via electronic mail, the EtO consumption logs, the Abators Operation and Installation Manual, the Abators inspection report, and the Abators preventive maintenance procedure, among other information.
53. On December 19, 2019, Respondent submitted via electronic mail to EPA a report titled “Initial Performance Test and Oxidation Temperature Continuous Monitoring System Performance Evaluation Test for ETO Catalytic Oxidizer” (“August 2000 Initial Performance Test Report”).
54. According to the August 2000 Initial Performance Test Report, Medtronic contracted with Panzardi-ERM/IT Corporation to conduct the August 2000 Initial Performance Test on all the catalytic oxidizers at the Sterilization Facility.
55. According to the August 2000 Initial Performance Test Report, the August 2000 Initial Performance Test was conducted by Respondent on August 9, 2000.
56. At the time of the August 2000 Initial Performance Test, Respondent was operating 13 sterilization chambers and their associated catalytic oxidizers.
57. According to the August 2000 Initial Performance Test Report, Respondent conducted an initial performance test on 1 of the 13 catalytic oxidizers while one of the sterilizer chambers was operated under its normal operating cycle. The test resulted in a 99% destruction removal

efficiency of EtO and an average EtO concentration during the first evacuation of 11.2 ppm at the outlet of the catalytic oxidizer.

58. Respondent did not apply for or seek approval of a waiver from EPA to exclude the other 12 catalytic oxidizers from the August 2000 Initial Performance Test.
59. On December 23, 2019, the EPA inspector reviewed the information provided by Respondent and EPA Region 2 Caribbean Environmental Protection Division's records and found that Respondent had not submitted a notification of compliance status report required under 40 C.F.R. § 63.9(h).
60. On June 2, 2020, Medtronic submitted to EPA, via electronic mail, a report dated May 28, 2020, titled "Excess Emissions and Continuous Monitoring System Performance Report and Summary Report: January 1, 2016 through December 31, 2019 Medtronic PR Operations Co."

### **CONCLUSIONS OF LAW**

Based on the Findings of Facts set forth above, EPA reaches the following conclusions of law:

61. Respondent is a "person" within the meaning of Section 302(e) of the Act.
62. Respondent is the owner and operator of the Facility with the meaning of Section 112(a)(9), 42 U.S.C. § 7412 (a)(9) of the CAA and 40 C.F.R. § 63.2.
63. The Facility is subject to the applicable requirements in NESHAP Subpart O.
64. Based on both visual observations and information provided by Respondent as described above, EPA has determined that:
  - a. Respondent is in violation of 40 C.F.R. §§ 63.360 and 63.10(e)(3) for failing to submit an excess emissions and continuous monitoring system performance report and/or summary report to EPA semiannually.

- b. Respondent is in violation of 40 C.F.R. § 63.363(a)(1) for failing to conduct an initial performance test on all 13 catalytic oxidizers using the procedures listed in 40 C.F.R. § 63.7 according to the applicability in Table 1 of § 40 C.F.R. § 63.360, the procedures listed in 40 C.F.R § 63.363, and the test methods listed in 40 C.F.R. § 63.365.
  - c. Respondent is in violation of 40 C.F.R §§ 63.9(h)(2)(i) and (ii) for failing to submit to EPA a notification of compliance status attesting to whether the source has complied with the relevant standard.
65. Respondent is in violation of RCAP Rule 204(H)(1) for failing to submit an air emissions source operating permit renewal application by January 20, 2017, or at least 60 days prior to the Permit's March 21, 2017 expiration date.

### **ENFORCEMENT**

Section 113(a)(1) and (3) of the CAA, provide that the Administrator may bring a civil action whenever, on the basis of any information available to the Administrator, the Administrator finds that any person has violated or is in violation of any requirement rule or permit issued under the provisions of Section 113 of the CAA. Administrator shall notify the person and the State in which the plan applies of such a finding. At any time after the expiration of thirty (30) days following the date this Notice of Violation is issued, the Administrator may, without regard to the period of violation:

- a. issue an order requiring such person to comply with the requirements or prohibitions of a SIP or permit;
- b. issue and administrative penalty order in accordance with CAA Section 113(d); or
- c. bring a civil action in accordance with CAA Section 113(b) for civil penalties and/or injunctive relief.

The amount of civil penalties that may be recovered for violations such as those discussed above of the CAA and its implementing regulations is set by statute at not more than \$25,000 per day for each violation, but has been adjusted over time as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Pub. L. 101-410), as amended by the Debt Collection Improvement Act of 1996, and most recently, by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (28 U.S.C. § 2461 note; Pub. L. 114-74, Section 701). For civil penalties for violations that occurred after November 2, 2015 and are assessed on or after December 23, 2020, this daily penalty maximum is adjusted to \$102,638 for judicial actions, and \$48,762 for administrative actions. *See* 40 C.F.R. Part 19, Table 2.

Furthermore, for any person who knowingly violates any requirements or prohibition of an applicable SIP and permit for more than 30 days after the date of the issuance of an NOV, Section 113(c) of the Act provides for criminal penalties or imprisonment, or both. In addition, under Section 306 of the Act, the regulations promulgated thereunder (40 C.F.R. Part 15), and Executive Order 11738, facilities to be utilized in federal contracts, grants and loans must be in full compliance with the Act and all regulations promulgated pursuant thereto. Violation of the Act may result in the subject facility or other facilities owned or operated by Respondent, being declared ineligible for participation in any federal contract, grant, or loan program.

### **PENALTY ASSESSMENT CRITERIA**

Section 113(e)(1) of the Act provides that if a penalty is assessed pursuant to Section 113 of the Act, EPA or the court, as appropriate, shall, in determining the amount of the penalty to be assessed, take into consideration the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violation as established by any credible evidence (including evidence other than the applicable test method),

payment by the violator of penalties previously assessed for the same violation, the economic benefit of non-compliance, the seriousness of the violation, and other factors as justice may require.

Section 113(e)(2) of the Act allows EPA or the court, as appropriate, to assess a penalty for each day of violation. In accordance with Section 113(e)(2) of the Act, EPA will consider a violation to continue for the date the violation began until the date Respondent establishes that has achieved continuous compliance. If Respondent proves that there was an intermittent day of compliance or that the violation was not continuous in nature, EPA will reduce the penalty accordingly.

### **OPPORTUNITY FOR A CONFERENCE**

Respondent may request a conference with EPA concerning the violations alleged in this NOV. This conference will enable Respondent with an opportunity to advise the Agency of any further information the EPA should consider with respect to the alleged violations and to present evidence bearing on the finding of violations, on the nature of the violations, and on any efforts it may have taken or proposes to take to achieve compliance. Respondent has the right to be represented by counsel. A request for a conference must be made within 10 days of receipt of this NOV. A request for a conference or other inquiries concerning the NOV should be made via electronic mail or in writing to:

Nancy Rodríguez, Chief  
Multimedia Permits and Compliance Branch  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency - Region 2  
City View Plaza II – Suite 7000  
#48 Road. 165 Km. 1.2  
Guaynabo, Puerto Rico 00968-8073  
Attn: Alex Rivera, Enforcement Officer  
rivera.alex@epa.gov

If you are represented by counsel, your counsel may contact:



Suzette M. Meléndez Colón  
Office of Regional Counsel  
U.S. Environmental Protection Agency - Region 2  
City View Plaza II – Suite 7000  
#48 Road. 165 Km. 1.2  
Guaynabo, Puerto Rico 00968-8073  
melendez-colon.suzette@epa.gov  
(787) 977-5822

By offering the opportunity for a conference or participating in one, EPA does not waive or limit its right to any remedy available under the CAA. Also, notwithstanding this NOV and the opportunity for conference, Respondent must comply with all applicable requirements of the CAA.

For United States Environmental Protection Agency, Region 2:

Date: July 29, 2021

For **Font, Jose** Digitally signed by Font, Jose  
Date: 2021.07.29 12:04:11  
-04'00'

Carmen R. Guerrero  
Director  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency - Region 2

To: Elvin J. Velez, Medtronic PR Facilities Manager, elvin.j.velez.santiago@medtronic.com  
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CEPD MPCB Air File  
ORC Air Chron File